K103793
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# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

**1. Trade (Proprietary) Name**

DURAFIBER Ag

**2. Common/Classification Name**

Common Name: Silver Absorbent, Gelling Dressing

Classification Name: Dressing

Classification Code: FRO

**3. Applicant's Name & Address**

Smith & Nephew, Inc.
970 Lake Carillon Drive
St. Petersburg, Florida 33716
Phone: 727-392-1261
Fax: 727-399-3468

**4. Contact Information**

Terry McMahon
Director, Regulatory Affairs and Quality, North America
Phone: 727-399-3785
Email: terry.mcmahon@smith-nephew.com

**5. Device Classification and Panel**

A final classification for "dressing" has not been implemented by the General and Plastic Surgery Devices Panel. At this time, however, classification code FRO is unclassified.

**6. Predicate Device**

Aquacel Ag (K080383)

The DURAFIBER Ag dressing that is the subject of this submission is substantially equivalent to other legally marketed burn and wound dressings. The DURAFIBER Ag dressing is substantial equivalent to Convatec, Aquacel Ag Wound Dressing (K080383). The subject device has all features and benefits associated with a fibrous gelling dressing and the added benefit of an antimicrobial dressing.

**7. Other Relevant Predicate Device**

ACTICOAT Flex 7 (K083113)

The specified silver content of ACTICOAT Flex 7 (K083113) is similar to and slightly higher of that of the subject device DURAFIBER Ag and is used on similar wound types. The device is therefore substantially equivalent in terms of silver content.

**8. Performance Standards**

No applicable performance standards have been established under Section 514 of the FD&C Act. Biocompatibility tests were done in conformance with relevant requirements of AAMI/ISO-10993. Additional standards applicable to the device include the following: ISO 13485, AAMI/ISO 11137-1, and AAMI/ISO 11137-2.

## 9. Intended Use

DURAFIBER Ag is an effective antimicrobial dressing that is intended to provide a moist wound environment for use in the management of partial and full thickness wounds including first and second degree burns. Examples of wounds types which indicated are:

- Chronic wounds including diabetic ulcers, leg ulcers, pressure ulcers and sores (partial & full thickness);
- surgical wounds left to heal by secondary intent;
- traumatic wounds;
- wounds that are prone to minor bleeding, such as wounds that have been mechanically or surgically debrided.

## 10. Device Description

DURAFIBER Ag is a non woven dressing made of cellulose and cellulose ethyl sulphonate with silver. The product is an absorbent fibrous dressing that gels on contact with wound fluid. The device provides effective antimicrobial properties intended to reduce or inhibit microbial colonization of the device.

The silver is present in the device in the form of silver chloride. Upon contact with wound fluid, silver ions are produced from the dissociation of silver and chloride atoms. The ionic form of silver is the active antimicrobial agent.

## 11. Biocompatability

The biocompatibility of DURAFIBER Ag dressing has been demonstrated through assessment according to ISO 10993-1: 2003 and appropriate *in vivo* and *in vitro* tests have been conducted using product that has been packaged and sterilised. These include cytotoxicity, sensitization, irritation, subchronic toxicity, and genotoxicity. These studies indicated that DURAFIBER Ag dressings are safe for their intended use.

Additionally, the effects of the device on wound healing have been evaluated in an animal model, and it was demonstrated that the device had no deleterious clinical effects compared with standard treatment.

## 12. Summary of Substantial Equivalence

The subject device is substantially equivalent to the predicate device Aquacel Ag (K080383). The subject device has similar physical and antimicrobial characteristics and provides similar functions to Aquacel Ag (K080383). The subject device and the predicate device Aquacel Ag (K080383) have similar design, materials and manufacturing methods. The intended use, indications and instructions for use for the subject and predicate devices are similar.

The safety of the antimicrobial agent, ionic silver, has been established by comparing the subject device to the predicate device ACTICOAT Flex 7 (K083113).

The subject device does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Terry McMahon
Director of Regulatory Affairs
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

MAY - 2 2011

Re: K103793
Trade/Device Name: DURAFIBER Ag
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 17, 2011
Received: March 22, 2011

Dear Terry McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): To be assigned by FDA K103793

Device Name: DURAFIBER Ag

Indications For Use:

DURAFIBER Ag is an effective antimicrobial dressing that is intended to provide a moist wound environment for use in the management of wounds of partial and full thickness wounds including first and second degree burns. Examples of wound types which indicated are:

- Chronic wounds including diabetic ulcers, leg ulcers, pressure ulcers and sores (partial & full thickness);
- surgical wounds left to heal by secondary intent;
- traumatic wounds;
- wounds that are prone to minor bleeding, such as wounds that have been mechanically or surgically debrided.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103793